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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/776,044	02/26/1997	MARGARET BYWATER	1614-178P	1463

2292 7590 07/08/2003

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/08/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/776,044

Applicant(s)

BYWATER ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 May 2003 and 26 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on May 5, 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/776,044 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1-10, 14, and 15 are pending and examined on merits.

### ***Claim Rejections - 35 USC § 112***

Claim 3 remains rejected for reason of record under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant argues in the response filed on 9-26-2002 (Paper No. 30) that mutation causing a frameshift in amino acid sequence in p53 or nonsense mutation which results in truncated p53 is more detrimental than missense mutation which causes single amino acid substitution. One in ordinary skill would agree with the applicant's argument that out-of frameshift and nonsense mutations are more detrimental to cancer patient because these mutations would knock out the function of affected region of p53. However, the claim as written, especially the conclusion step of the claim says that any mutation in the conserved region II and V of p53 is indicative of poor outcome of patient survival whereas any mutation in the conserved region of III

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and IV is indicative of positive outcome of patient survival. This is interpreted as a nonsense mutation in the conserved region III results in better outcome than a nonsense mutation in the conserved region V. A nonsense mutation in the conserved region III will abolish the function of the conserved region V because the stop codon is placed well before the region V. Therefore, it is concluded that a mutation in the conserved region III could not result in better outcome than a mutation in conserved region of V. This kind of analysis could also be done with out-of frame shift mutation. Any out-of-frame shift mutation in closer to N-terminal p53 is worse than any out-of-frame shift mutation in C-terminal end for the same reason above.

***Claim Rejections - 35 USC § 102***

Claim 15 remains rejected for reason of record under 35 U.S.C. 102(e) as being anticipated by Vogelstein et al (US PAT 5,527,676; issued June 18, 1996; effective filing date of December 6, 1989).

Applicant argues that Vogelstein et al fail to disclose a method for prognostication of the development of neoplasia in a human patient. However, this argument is not persuasive because Vogelstein et al teach at column 1 (see also page 7 Paragraph # 13 of the prior Office action, Paper No. 25) that the reason for undertaking the study disclosed in the patent is to define the particular genetic region in the short arm of chromosome 17 responsible for progression of curable adenoma to lethal carcinoma. Vogelstein et al teach that that specific genetic region is the gene encoding p53 and mutation in that specific genetic region is responsible for progression of benign, curable disease to lethal carcinoma (indicative of poor patient survival), thus

Vogelstein et al teach a method of prognostication of the development of neoplasia by detecting a mutation in p53. The broadly written claim 15 thus reads on the prior art.

***Claim Rejections - 35 USC § 103***

Claims 1, 2, 4-10, and 14 remain rejected for reason of record under 35 U.S.C. 103(a) as being unpatentable over Vogelstein et al as applied to claim 15 above, and in view of Elledge et al (Breast Cancer Res. Treat. 27, 95-102, 1993), and of Callahan (J. Natl. Cancer Institute, 83, 826-7, 1992) and further in view of Hedrum (IDS, BioTechniques, 17, 118-29, 1993).

Applicant argues since Vogelstein et al above do not teach method of prognostication of neoplasia, this rejection also falls. However, the Office interprets that broadly written claim 15 reads on Vogelstein et al, thus this rejection also stands.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.


Application/Control Number: 08/776,044

Page 5

Art Unit: 1642

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu  
July 8, 2003

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800** 1600